Report on Incident of Testing Cancer Drugs in Kerala

2262. SHRI A. VIJAYA RAGHAVAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the report submitted by the Committee to examine alleged incident of testing cancer drugs on human being during the year 2001 without following standards in the Cancer Institute at Thiruvananthapuram has been examined by competent authority;

(b) whether there is any difference of opinion in findings and fixing responsibility between the studies of ICMR and the Committee appointed by Government of Kerala;

(c) if so, the details including findings of both the studies; and

(d) the remedial measures taken or to be taken by Government in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (d) As per the findings of the investigation team consisting of representatives from Dte. General of Health Services, Indian Council of Medical Research and Central Drug Standard Control Organization and Inquiry Officer, appointed by Government of Kerala, there is no difference of opinion of the expert. Both the reports concluded that the Regional Cancer Centre, Thiruvanthapuram has not used any banned drug as alleged in the complaint. However, there have been some procedural lapse for which the Director, Regional Cancer Centre, Thiruanthapuram was served a show-cause notice and was directed to suspend all ongoing clinical trials for a period of six months.

The RCC has also been directed to reconstitute its Institutional Ethical Committee in accordance with the ethical guidelines issued by ICMR. Further, a representative of ICMR would now be required to be on the institutional Ethical Committee of RCC, Thiruvananthapuram.

Government has already amended rule 122DA under the Drugs and Cosmetics Act providing for written permission to be obtained from Drugs Controller of India for clinical trials of any new drug

whether for clinical investigation or any experiment, Good Clinical Practices (GCP) guidelines have also been published to streamline procedure for conducting clinical trials including code of ethics to be followed for all clinical trials.

Drive Against Spurious Drug Sellers and Manufacturers

†2263. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of persons apprehended under the drive being carried out against spurious drug sellers and manufacturers; and

(b) the action being taken against these persons?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) As per the feedback received from State Licensing Authorities, in all 68 persons have been apprehended since 1.4.2000 to 1.8.2001 for manufacturing and trading of spurious drugs in the States of Bihar, Gujarat, Maharashtra, Rajasthan, U.P., Delhi and A.P., Delhi Police in association with drugs Control Department of Govt. of NCT of Delhi and Central Drugs Standard Control Organisation (CDSCO), North Zone in a joint raid carried out in February 2002 have also apprehended four persons for manufacturing and trading of spurious drugs. Police seized large haul of fake drugs moving in the inter-State commerce in this raid.

(b) the concerned State Licensing Authorities initiated punitive as per the provisions of Drugs and Cosmetics Act, 1940 and rules thereunder against such persons.

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†Original notice of the question was received in Hindi.